



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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|---|---|--|--|
| Applicant's or agent's file reference 331.03471 | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/AL 03/00254 | International filing date (day/month/year) 26.03.2003 | Priority date (day/month/year) 26.03.2002 | |
| International Patent Classification (IPC) or both national classification and IPC A61M25/00 | | | |
| Applicant HALPERIN, Haim | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 6 sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | | |
| Date of submission of the demand 27.10.2003 | | Date of completion of this report 03.11.2004 | |
| Name and mailing address of the International preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840 | | Authorized Officer Jameson, P Telephone No. +49 30 25901-580  | |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**International application No. **PCT/IL 03/00254****I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-16, 18-20 as originally filed
17 filed with telefax on 23.02.2004

Claims, Numbers

10-47 filed with telefax on 23.02.2004
1-9 filed with telefax on 20.10.2004

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-47 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-47 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-47 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-5 885 258 (BESSELINK PETRUS A ET AL) 23 March 1999 (1999-03-23)

D2: US-A-4 564 014 (CHIN ALBERT K ET AL) 14 January 1986 (1986-01-14)

1. Independent Claim 1

In the light of the documents cited in the international search report, it is considered that the invention as claimed in the independent claim meets the criteria mentioned in Article 33 (1) PCT, i.e. it appears to be novel, to involve an inventive step and to be industrially applicable.

2. Further Comments

- 2.1 According to the requirements of Rule 11.13(m) PCT the same feature shall be denoted by the same reference sign throughout the application. This requirement is not met in view of the use of skin 102 (page 1, 13, 18), surface 102 (page 9), arm 102 (page 10), body tissue 102 (claim 1); and catheter front inlet 134 (page 1-2, 9, 13, 14, 19, 20), catheter tip 134 (page 10, 17), port 134 (page 14, 15) and aperture 134 (claim 1).
- 2.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D2 is not mentioned in the description, nor are these documents identified therein.
- 3.3 The features of the dependent claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 3.4 The vague and imprecise statement in the description on page 20 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to

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interpret them (see also the PCT Guidelines, III-4.3a).

- 3.5 As explained below, some of the features in the apparatus dependent claims 5-12, 21-24 and 44-45 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from these claims, contrary to the requirements of Article 6 PCT.

The impediment is not part of the apparatus and therefore the claims 5-10 defining said impediment are related to the method of using the apparatus, not to the technical features of the apparatus. Claims 11-12 relating to the period of implantation do not define a technical feature which adapts the hollow tube to be implanted for such periods. Claims 21-24 related to fluid withdrawal or exchange are dependent on claim 1, which has the text "purpose of fluid intake"; and moreover are related to a method of using the apparatus. Claims 44 and 45 have no technical feature which adapts the extensions for either type of vessel.